

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

John F. SHANLEY *et al.*

Application No.: **10/824,124**

Filing Date: 13 April 2004

For: Expandable Medical Device with S-Shaped
Bridging Elements

Art Unit: 3731

Examiner: Bui, Vy Q.

Attorney Ref. No.: P003 C5

RESPONSE UNDER 37 C.F.R. § 1.111

Mail Stop AMENDMENT

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

In response to the Office Action dated 17 October 2006, which set a three-month shortened statutory period of response thereto, favorable reconsideration, reexamination, and allowance of this patent application are respectfully requested in view of the following remarks.

Rejection under 35 U.S.C. § 102

In the Office Action, beginning at page 2, Claims 1-10 and 17 were rejected under 35 U.S.C. § 102(e), as reciting subject matters that allegedly are anticipated by *Ehr*. Applicant respectfully requests reconsideration of this rejection.

Applicant has previously described some aspects of the present invention, for example in the Amendment filed 21 September 2006; Applicant will therefore not further burden the record with a redundant summary, and merely incorporates by reference those descriptions.

Claim 1 relates to an expandable medical device having a combination of elements including, *inter alia*, a plurality of S-shaped bridging elements connected between interconnected ends of struts in adjacent cylindrical tubes, wherein the bridging elements are connected entirely above a midline of V-shapes on one cylindrical tube and entirely below the midline of V-shapes on an adjacent cylindrical tube, wherein the bridging elements cross the midline of the V-shapes three times, and wherein said adjacent struts interconnected at

alternating ends define an apex for each V-shape, and wherein said midlines connect directly opposed V-shape apices directed at each other.

Claim 10 relates to an expandable medical device having a combination of elements including, *inter alia*, a plurality of S-shaped bridging elements connected between the interconnected ends of the struts in adjacent cylindrical tubes, wherein each of the bridging elements cross a midline of the V-shapes three times and are connected entirely above the midline of the V-shapes on one cylindrical tube and entirely below the midline of the V-shapes on an adjacent cylindrical tube.

Claim 17 relates to an expandable medical device having a combination of elements including, *inter alia*, a plurality of S-shaped bridging elements connected between interconnected ends of struts in adjacent cylindrical tubes, wherein the bridging elements are connected entirely above a midline of V-shapes on one cylindrical tube and entirely below the midline of V-shapes on an adjacent cylindrical tube, wherein the bridging elements cross the midline of the V-shapes three times, wherein the adjacent struts interconnected at alternating ends define an apex for each V-shape, and wherein the bridging elements extend between directly opposed V-shape apices in a first of said plurality of cylindrical tubes and said V-shape apices in a second of said plurality of cylindrical tubes.

The prior art, including *Ehr*, fails to identically disclose or describe a device having the claimed combination of elements.

The Office Action included an annotated version of *Ehr*'s Fig. 16 (reproduced herein), yet the totality of the written explanation for the rejection of the claims over *Ehr* was:

As to claims 1-10 and 17, *Ehr*-'633 (please refer to Fig. 16 reproduced on next [sic] page) discloses a stent having S-shape [sic] bridging elements crossing three times midlines of V-shapes as recited in the claims.

With reference to the annotated version of Fig. 16 of *Ehr* from the Office Action, Applicant first notes that the Office Action's version of Fig. 16 has been partially shaded, with the words "S-shaped bridging elements" indicating shaded struts 13. Applicant also points out that, although there are many fonts and typefaces that may be available for use in the printed English language, and therefore that the letter "S" may have many forms (*e.g.*: S, S, S, S, S, S, S, S, S, S, and S, as well as others), all the forms of the letter "S" share an attribute: they all include a line that changes direction only twice. Yet, the Office Action has shaded portions of *Ehr*'s device, including numerous struts 13, **which changes direction at least twelve (12) times**. It is quite notable that the Office Action's annotated Fig. 16 of *Ehr* uses two arrows to point to the struts 13, which would suggest that the Office Action recognizes that an "S-shape" cannot be the entire shaded portion; yet the above-quoted explanation of the rejection seems to state that it is the entire shaded portion of *Ehr* that is allegedly read on by the claimed combinations.

Instead of the entire shaded set of struts 13 in *Ehr*'s Fig. 16 being a single "S-shaped bridging element" as required by the combinations of the pending claims, it is in fact, from top to bottom (as reproduced herein): a portion of a strut 13 that does not cross any midline; eleven (11) struts 13, the ends of which are interconnected to form a series or chain, each of which struts 13 cross a midline only once; and a last portion of a strut 13 that also does not cross any midline. Furthermore, the annotation of Fig. 16 of *Ehr* presented in the Office Action plainly shows that the struts 13 that actually do connect to the segments 12 are not fully S-shaped; instead, they are only a portion of such an element, and therefore there are no S-shaped struts 13 of *Ehr* connected to a cylindrical tube of V-shapes entirely above and below a midline, as recited in the pending claims.

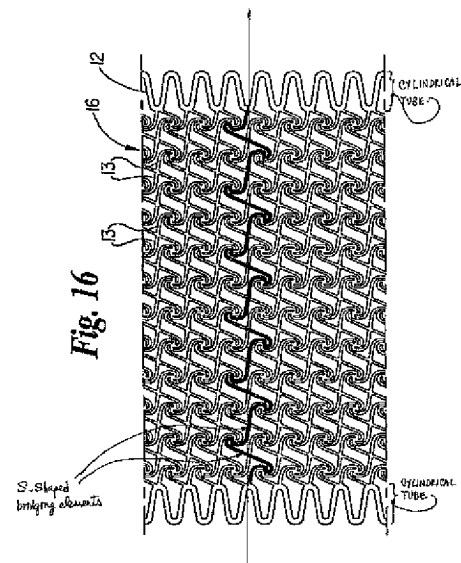


Fig. 16 of *Ehr*, from 10/17
Office Action

Accordingly, *Ehr* fails to disclose a device that includes each and every limitation recited in the combinations of Claims 1-10 and 17.

For at least the foregoing reasons, Applicant respectfully submits that the subject matters of Claims 1-10 and 17 are not anticipated by *Ehr*, are therefore not unpatentable under 35 U.S.C. § 102, and therefore respectfully requests withdrawal of the rejection thereof under 35 U.S.C. § 102.

Rejection under 35 U.S.C. § 103(a)

In the Office Action, beginning at page 4, Claims 11-16 were rejected under 35 U.S.C. § 103(a), as reciting subject matters that allegedly are obvious, and therefore allegedly unpatentable, over *Fischell* in view of *Jang*. Applicant again respectfully requests reconsideration of this rejection.

Applicant first notes that each of Claims 11-16 depend from Claim 10, and are therefore allowable for at least the same reasons. Because Claim 10 is not rejected over *Fischell* in view of *Jang*, and because Claim 10 is patentable over *Ehr* for the reasons presented above, Applicant respectfully submits that Claims 11-16 are allowable by virtue of their dependence from Claim 10.

Claim 10 relates to an expandable medical device having a combination of elements including, *inter alia*, a plurality of S-shaped bridging elements connected between interconnected ends of struts in adjacent cylindrical tubes, wherein each of the bridging elements cross a midline of the V-shapes three times and are connected entirely above the midline of the V-shapes on one cylindrical tube and entirely below the midline of the V-shapes on an adjacent cylindrical tube.

The prior art, including *Fischell* and *Jang*, fails to disclose, describe, or suggest the combinations of elements recited in Claims 10-16.

Applicant previously (*e.g.*, in the Amendment filed 21 September 2006) described certain features and objects of the devices of *Fischell* and *Jang*, and will therefore not burden the record with a rote reproduction of those discussions; they too are incorporated by reference in their

entireties.

The Office Action changed the putative rationale supporting the rejection of Claim 10 *et seq.* between the Office Actions of 18 April and 17 October. The most recent Office Action, apparently recognizing that the April 18th Office Action's rationale was faulty, stated:

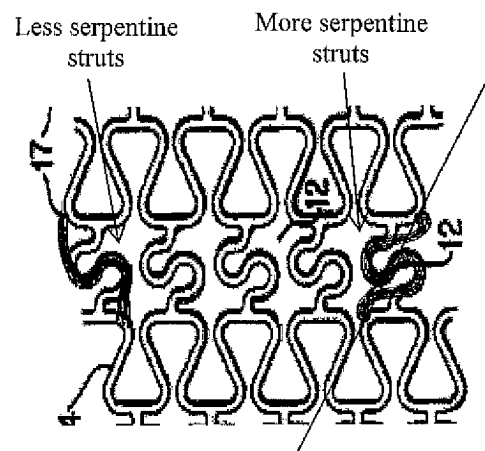
It would have been obvious . . . to move the connecting points to the locations as shown in modified Fischell-'971 [sic] stent in view of Jang-'053 (please, see Fig. 2 on next [sic] page) **for this modified configuration is just another choice of design for Fischell-'971 stent [sic] in view of Jang-'053.**

(emphasis added)

Applicant strongly disagrees.

The hypothetical construct alleged to be obvious in the Office Action would destroy the goal of *Fischell*'s stent: modification of *Fischell*'s undulating S-struts, by replacing them with or modifying them in view of *Jang*'s, would result in a stent having limited or no additional expandability after deployment of the stent in the patient's vasculature. The hypothetical combination of *Fischell* with *Jang* therefore would destroy *Fischell*'s device's functionality for its intended purpose. Applicant respectfully submits that a person of ordinary skill in the art would not seek to emasculate *Fischell*'s stent by modifying it in view of *Jang*.

Assuming, *arguendo*, that the skilled artisan would, despite the fact that *Fischell* strongly teaches away from a combination with *Jang*, look to modify *Fischell*'s stent structure with *Jang*'s connecting column's strut sets, the resulting hypothetical stent would still not include each and every element recited in the combinations of the pending claims. The Office Action again kindly includes, at page 5, a marked-up portion of figure 2 of *Fischell*, annotated with a modified S-strut and a diagonal line.



Annotated Fig. 2 of *Fischell*,
from 6 Jan. '06 Amendment

In the Amendments filed 6 January and 21 September 2006, Applicant included a reproduction of a marked up version of that illustration (reproduced herein, with additional annotation), which includes an alternative hypothetical combination of *Fischell* and *Jang*. Applicant respectfully submits that the illustration contained on page 5 of the Office Action would not be the stent structure the skilled artisan would arrive at from a full and fair reading of *Fischell* and *Jang*, were the routineer to be motivated to combine the two documents. Instead, the illustration on page 5 is the result of an impermissible hindsight reconstruction of the claimed subject matter using Applicant's own specification as a guide, and therefore a *prima facie* case of obviousness has not been made.

Applicant respectfully submits that, were one of ordinary skill in the art to combine *Fischell* with *Jang*, the result would be a *Fischell* stent with, essentially, *Jang* connecting column strut sets. That is, instead of becoming more undulating, as suggested in the page 5 illustration in the Office Action, the result would be a less serpentine S-strut which extends diagonally between *Fischell*'s struts 13, 14 only once, as does *Jang*'s connecting strut sets. Nowhere in *Fischell*, *Jang*, or any other evidence in the record, is there motivation to make *Fischell*'s S-struts **more serpentine**, and indeed *Jang* specifically teaches away from that configuration by disclosing **less serpentine** elements. Accordingly, Applicant respectfully submits that a *prima facie* case of obviousness has not been made in the Office Action.

The Office Action's rationale for modifying *Fischell*'s S-struts, "just another choice of design", falls flat in view of *Fischell*'s stated purposes and *Jang*'s disclosure. The Office Action notably provides no motivation why a person of ordinary skill in the art would 'change the design' of *Fischell*'s device, as the Office Action alleges would have been obvious, in particular in view of the negative effects noted by Applicant on this record. The Office Action's allegation of 'choice of design' inappropriately attempts to minimize Applicant's claimed combinations, without justification. The fact remains that *Jang* plainly points towards a **less serpentine strut, not a more serpentine strut** as drawn in the Office Action. The only source of motivation to make the modification of *Fischell*'s S-struts, alleged to be obvious in the Office Action, is Applicant's own specification, which is an impermissible hindsight reconstruction of Applicant's

claimed combination.

For at least the foregoing reasons, Applicant respectfully submits that the subject matters of Claims 10-16, each taken as a whole, would not have been obvious to one of ordinary skill in the art at the time of Applicant's invention, are therefore not unpatentable under 35 U.S.C. § 103(a), and therefore respectfully requests withdrawal of the rejection thereof under 35 U.S.C. § 103(a).

Conclusion

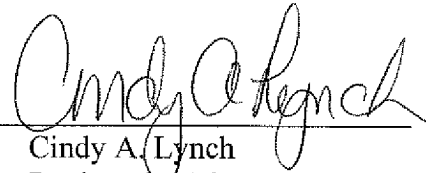
Applicant respectfully submits that the present patent application is in condition for allowance. An early indication of the allowability of this patent application is therefore respectfully solicited.

If Mr. Bui believes that a telephone conference with the undersigned would expedite passage of this patent application to issue, he is invited to call on the number below.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. If, however, additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and the Commissioner is hereby authorized to charge fees necessitated by this paper, and to credit all refunds and overpayments, to our Deposit Account 50-3100.

Respectfully submitted,

By: _____



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